## PATENT COOPERATION TREATY

NTEF	RNATIONAL SEAR	CHING AUTHO	DRITY		DOT
To:					PCT
see form PCT/ISA/220				WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43 <i>bis</i> .1)	
				Date of mailing (day/month/year) se	ee form PCT/ISA/210 (second sheet)
	icant's or agent's file form PCT/ISA/22			FOR FURTHER ACTION . See paragraph 2 below	
	national application N TÆP2004/052421		International filing date (a 04.10.2004	day/month/year) Priority date (day/month/year) 06.10.2003	
	national Patent Class	sification (IPC) or	both national classification	and IPC	
	licant				
	LVIAS AG				
1.	Box No. I Box No. II Box No. II Box No. III Box No. IV Box No. V	Basis of the operation	ment of opinion with rega of invention	ard to novelty, invent	tive step and industrial applicability o novelty, inventive step or industrial atement
	☐ Box No. VI	Certain docum		P. Att.	
	☑ Box No. VII		ts in the international app vations on the internation		
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2.	written opinion of the applicant ch International Bu will not be so co	international pro of the Internation ooses an Authoreau under Rule nsidered.	nal Preliminary Examinin rity other than this one to e 66.1 <i>bis</i> (b) that written o	ig Authority ("IPEA"), to be the IPEA and the opinions of this Interr	rill usually be considered to be a . However, this does not apply where he chosen IPEA has notifed the national Searching Authority
	aubmit to the ID	EA a written repended a contract of the contra	dy together where appro	onriate with amendi	e IPEA, the applicant is invited to nents, before the expiration of three on of 22 months from the priority date,
	For further optic	ons, see Form F	PCT/ISA/220.		
3.	For further deta	ils, see notes to	Form PCT/ISA/220.		
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# WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

10/574857 IAPO Toc'd PCT/PTO 06 APR 2006 International application No. PCT/EP2004/052421

	Box N	lo. I	Basis of the opinion			
1.	With regard to the <b>language</b> , this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.					
	la	ngua	ninion has been established on the basis of a translation from the original language into the following ge , which is the language of a translation furnished for the purposes of international search Rules 12.3 and 23.1(b)).			
2.	With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:					
	a. type of material:					
		a se	equence listing			
		tabl	e(s) related to the sequence listing			
	b. forn	o. format of material:				
		in w	vritten format			
		in c	omputer readable form			
	c. time	e of fi	ling/furnishing:			
		cor	tained in the international application as filed.			
		file	d together with the international application in computer readable form.			
		fur	nished subsequently to this Authority for the purposes of search.			
3.	h	nas be copies	ition, in the case that more than one version or copy of a sequence listing and/or table relating thereto sen filed or furnished, the required statements that the information in the subsequent or additional is identical to that in the application as filed or does not go beyond the application as filed, as priate, were furnished.			
4	Additional comments:					

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

No: Claims

1-10

Inventive step (IS)

Yes: Claims

No: Claims

1-10

Industrial applicability (IA)

Yes: Claims

1-10

No: Claims

2. Citations and explanations

see separate sheet

#### Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

#### Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

#### Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: WO 03/026797 A2 D2: WO 01/51919 A2 D3: WO 02/052919 A2

D4: R. HILFIKER ET AL.: "Polymorphism-integrated approach from high-throughput screening to crystallization optimization" JOURNAL OF THERMAL ANALYSIS AND CALORIMETRY, vol. 73, no. 2, 2003, pages 429-440.

D5: WO 00/60345 A1

2. D1-D4 disclose methods for the generation and detection of crystallizing compounds using arrays of vessels (e.g. micro-titre plates) so that high-throughput screening of different parameters may be assessed and the properties of the resulting solid forms may be analysed in parallel. Among the possible starting solutions for the solid form, the documents disclose the use of solvates and amorphous forms in, for example, saturated or supersaturated solutions. After the crystallization is carried out, the array plate comprise a variety of solid-forms which may then be identified and related to the parameters being studied. D1 also discloses devices for carrying out such methods comprising flow-through seals connected to one or more gas sources or vacuum pumps. D1-D4 also disclose apparatus comprising arrays of vessels, means for heating/cooling, stirring and means for detecting (e.g. Raman spectroscopy) the resulting solid forms. (See passages cited in the International Search Report.)

D5 discloses methods of screening and analysing crystal growth conditions. The method comprises the use of a microarray of vessels comprising heating/cooling means as well as means for stirring the samples. Once the crystallisation has been carried out the array of solid-forms (e.g. amorphous) are analysed using, for example, microscopy. (See passages cited in the International Search Report.)

Therefore, the subject-matter of claims 1-10 is not novel and does not fulfill the requirements of Article 33(2) PCT.

3. The applicant's attention is drawn to the fact that high-throughput screening of crystallization conditions and compositions is well known in the art, as the cited documents illustrate.

#### Re Item VII

#### Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D3-D5 is not mentioned in the description, nor are these documents identified therein.

#### Re Item VIII

### Certain observations on the international application

- 1. In claim 1, the feature "... the solutions of amorphous compounds [...] corresponding crystalline compound." attempts to define the subject-matter in terms of the result to be achieved, it does not contain any technical features (elements of the solution) necessary for achieving the result (Article 6 PCT). The same objection applies to claims 3-5.
- 2. The last paragraph of claim 10 does not contain any features that further characterise the apparatus (Article 6 PCT).